IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

AMERITOX, LTD., and
MARSHFIELD CLINIC, INC.,

Plaintiffs,

v.

MILLENNIUM HEALTH, LLC,

Defendant.

OPINION AND ORDER

13-cv-832-wmc

Plaintiffs Ameritox, Ltd., and Marshfield Clinic, LLC allege that defendant Millennium Health, LLC infringes two of their patents: U.S. Patents No. 7,585,680 ("the '680 patent"), purporting to describe a method for drug screening and compliance protocols for one sample of urine from a patient on a prescribed medication regimen; and 7,785,895 ("the '895 patent"), purporting to describe a similar method for one biological sample generally. (*See* Am. Compl., Exs. A, B (dkt. ##106-1, 106-2).) On February 19, 2015, the court *granted* Millennium's motion for summary judgment as to the '895 patent and *denied* it as to the '680 patent. (2/19/15 Op. & Order (dkt. #215).)

Pursuant to Rules 54(b) and 59(e) and 28 U.S.C. § 1292(b), Millennium moves the court for reconsideration or, in the alternative, certification of the issue of patent eligibility of the '680 patent for interlocutory appeal and stay of proceedings pending appeal. (Def.'s Mot. (dkt. #220).) Having considered the relevant materials, the court will deny Millennium's motion for reconsideration of this court's denial of its motion for summary judgment on the '680 patent as invalid under § 101, in substantial part because additional information will be provided at trial, as well as its paradoxical request for

certification of an interlocutory appeal that would keep both this court and the Federal Circuit from considering this supposed, additional evidence.

BACKGROUND

The court's analysis of patent eligibility under 35 U.S.C § 101 was central to its summary judgment decision with respect to both patents. That analysis resulted in the court's finding of an "inventive concept" -- that is "an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'" *See Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)). In so holding, the court found that the '680 patent afforded a new and improved result, solving a problem that was articulated in the specification itself. (2/19/15 Op. & Order (dkt. #215) 45-47.) The court (1) criticized Millennium's flawed analysis of § 101, which ignored the teachings in *Alice* that required elements of a claim be considered as a whole; and (2) emphasized the point that there was no evidence or rationale in the record on summary judgment that supported a finding as a matter of undisputed fact that the combination of the steps in claims were conventional. (*Id.* at 48-49.) In the end, the court held that Millennium had not met "its burden of producing 'clear and convincing' evidence that the combination taught in the '680 patent was known," much less undisputed evidence of such. *Id.* at 50.

The court also considered "evidence of combination" to help "guard against hindsight bias." (*Id.*) In the court's view, Millennium's expert engaged in exactly that by failing to join the proverbial dots of the invention in a rational way. Next, the court

reasoned that "Millennium ha[d] failed to offer any evidence that someone in the scientific community would have even 'thought' to combine the claimed elements." (*Id.* at 52.) On the contrary, the court found the evidence on summary judgment supported a finding that the scientific community would not have thought to combine the normalization and the comparative step. Not only did Millennium's expert *not* provide a rationale to find otherwise, but because Millennium did not supply anything in the prior art that would point to that conclusion. Instead, what evidence Millennium did supply cut heavily against their preferred position.

Finally, the court found Millennium failed to supply evidence of preemption, especially in the face of evidence proffered by Ameritox that showed a lack of preemption. (*Id.* at 55.) Indeed, in its reply brief, Millennium still failed to controvert Ameritox's evidence in any meaningful way, precluding a finding of patent ineligibility on summary judgment.

OPINION

I. Motion to Reconsider

In turning to the specific arguments raised in its motion, Millennium criticizes the court's finding that the combination of steps (a) through (f), and particular of the use of creatine to normalize urine, was novel.[1] (Def.'s Mot. (dkt. #220).) This criticism highlights a fundamental disconnect in defendant's argument: since the court only

[1] Millennium found no fault with the court's preemption analysis, presumably because a similar analysis supported invalidating the '895 patent.

denied *Millennium's* motion for summary judgment, arguing that there is contrary evidence merely suggests a factual dispute that requires a trial.

Even if the court were incorrect with respect to that finding, this alone would not provide a basis to grant Millennium's motion as the other stated reasons either independently or in combination adequately justify the court's conclusion. For example, Millennium finds no error in the court's analysis of the Supreme Court's decision in *Diamond v. Diehr*, 450 U.S. 175, 185 (1981), and the Federal Circuit's more recent decision in *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014), which supported a holding that the '680 patent solved "a unique problem with respect to drug testing technology" -- making it eligible for patent protection under 35 U.S.C § 101. (2/19/15 Op. & Order (dkt. #215) 47.)

Regardless, Millennium's criticism of the court's analysis under the *Alice* framework is faulty. Millennium's motion primarily criticizes the court for conflating 35 U.S.C § 101 patent eligibility requirements with §§ 102 and 103 requirements. Millennium took particular issue with the court's finding that it "failed to offer any evidence that someone in the scientific community would have even 'thought' to combine the claimed elements," and the related finding that prior art steered a skilled artisan away from combining creatinine normalization with the other steps in the '680 patent -- concluding that "a normalization step that others skilled in the art had rejected as unreliable can hardly be considered conventional in the § 101 context." (2/19/15 Op. & Order (dkt. #215) 52-54.)

Among others, this argument ignores that Millennium itself *squarely* argues the relevance of this factor in assessing the eligibility of the '680 patent under § 101. For example, Millennium filed a Notice of Supplemental Authority (dkt. #194), bringing to the court's attention, for purposes of its § 101 analysis, *In re BRCA1- and BRCA2- Based Hereditary Cancer Test Patent Litigation*, 774 F.3d 755 (Fed. Cir. 2014). With respect to the "step one of the *Alice* framework," the court held that case was binding. (2/19/15 Op. & Order (dkt. #215) 42.) *BRCA1* was not only relevant to step one, it was also relevant to step two of the *Alice* framework. Indeed, a unanimous panel held:

> The second paragraphs of claims 7 and 8 do nothing more than spell out what practitioners *already knew* -- how to compare gene sequences *using routine, ordinary techniques.* Nothing is added by identifying the techniques to be used in making the comparison because those comparison techniques were the ***well-understood, routine, and conventional techniques that a scientist would have thought*** *of* when instructed to compare two gene sequences.

Id. at 764 (emphasis added). As the court explained in its summary judgment opinion, this passage also echoed much of what the Supreme Court has held in recent cases. (2/19/15 Op. & Order (dkt. #215) 37 (discussing *Mayo*, 132 S. Ct. at 1298).)

In light of these Supreme Court and Federal Circuit decisions, the court finds no error in considering for § 101 purposes whether those skilled in the art would have "thought" to combine the claimed elements. Far from an erroneous "conflation" of legal principles (Def.'s Mot. (dkt. #22) 3), this approach fairly applies Supreme Court and Federal Circuit precedent, as this court is required to do.

Second, Millennium argues that even if the court's approach was correct, the court erred in concluding that the claimed steps were novel or inventive over the prior art.

While Millennium asserted that "[n]ormalizing urine samples via a metabolite/creatinine ratio has been routine and conventional practice for over 40 years" (Def.'s Opening Br. (dkt. #130) 76; *see also* Def.'s PFOFs (dkt. #127) ¶ 259), the evidence -- two articles -- failed to provide the support claimed. Indeed, the George Article does *not suggest the use of metabolite/creatinine in combination* with the other steps in the '680 patent was routine. On the contrary, the authors of that article found that it was an unreliable method. Specifically, the George Article expressly stated:

- "there is too large of an interindividual variation to use urinary excretion concentrations of methadone or EDDP as markers of compliance";
- urinary excretion testing "would point to a lack of suitability of using urine concentrations of EDDP or methadone as markers of compliance"; and
- "the only reliable method available to monitor methadone compliance is the use of plasma methadone drug testing."

(Mandel Decl., Ex. 43 (dkt # 129-43) 84-85.) Each of these observations support the court's reading of the evidence on summary judgment that at the time of the invention, blood testing was the only reliable (and routine) method to determine whether a patient was complying with a prescribed drug regimen, rather than use of metabolite/creatinine ratio in combination with other steps disclosed in the '680 patent. (2/19/15 Op. & Order (dkt. #215) 9.)

For all of these reasons, the court had little hesitation in finding "a normalization step that others skilled in the art had rejected as unreliable can hardly be considered conventional in the § 101 context." (2/19/15 Op. & Order (dkt. #215) 9.) Since this reasoning is tailored to the case law and evidence that *Millennium itself* put before the

court, it provides no basis to unravel the court's summary judgment decision simply because it does not sit well with Millennium's preferred position. *Cf. Liebel-Flarsheim Co. v. Medrad, Inc.,* 481 F.3d 1371, 1380 (Fed. Cir. 2007) *(*"beware of what one asks for, might be applicable here").

Still, Millennium is right to point out, as Justice Breyer did in *Mayo*, that "in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap," though it "need not always be so." *Mayo*, 132 S. Ct. at 1304. Millennium contends that additional prior art relevant to §§ 102 and 103 will undermine plaintiffs' "innovative concept" assertion, albeit without providing much in the way of specifics. (Def.'s Mot. (dkt. #220) 8-10.) Whatever the merit of this argument, the court again can find no reason to revisit its decision on Millennium's motion for summary judgment. At most, the court will deny Millennium's motion for reconsideration, leaving for another day whether the court may take the next step of finding as a matter of law that the patent is eligible and entering judgment in favor of Ameritox on Millennium's § 101 challenge to the '680 patent.

II. Certification for Interlocutory Appeal

In the alternative, Millennium seeks an order certifying this issue to the Federal Circuit for interlocutory appeal pursuant to 28 U.S.C. § 1292(b). Given that trial is less than a month away and the prejudice that could flow to Ameritox if the district court proceedings were put on hold until after an appellate determination, the court declines to certify this issue for interlocutory appeal. If anything, Millennium's assertion that the

trial will *inform* the § 101 issue generally fundamentally contradicts its argument that skipping the trial would advance the resolution of the parties' dispute under Rule 54(b). *See* 28 U.S.C. § 1292(b) (requiring the court to consider whether an "immediate appeal from the order may materially advance the ultimate termination of the litigation"); *see also Rembrandt Social Media, LP v. Facebook, Inc.*, 561 Fed. Appx. 909, 912 (Fed. Cir. 2014) (denying petition for interlocutory appeal, in part, because such an appeal would not "materially advance the ultimate termination of the litigation").

ORDER

IT IS ORDERED that defendant Millennium's motion for reconsideration or, in the alternative, certification for interlocutory appeal and stay of proceedings pending appeal (dkt. #220) is DENIED.

Entered this 19th day of March, 2015.

BY THE COURT:

/s/

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William M. Conley
District Judge